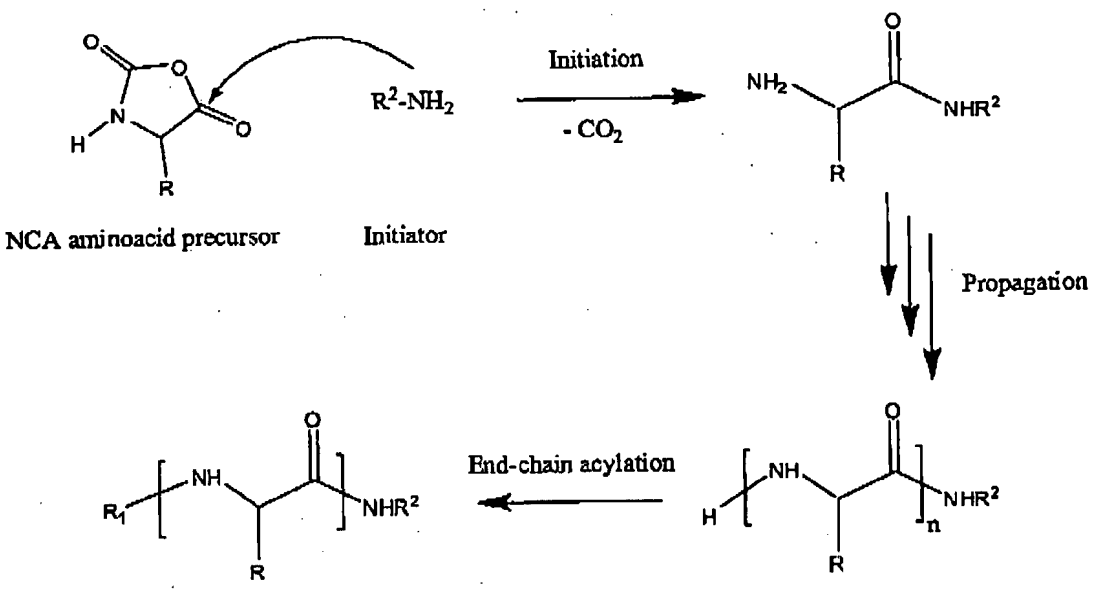
REMARKS

The Examiner rejected Claim 2 under 35 U.S.C. § 112, first paragraph, asserting that the amendment to Claim 2 changing the definitions of R^1 and R^2 lacked descriptive support. Office Action at 2. The preliminary amendment filed August 29, 2006, attached hereto, amended the specification to correct a typographical error contained the descriptive support for these changes. Applicants, therefore, respectfully request the Examiner withdraw the rejection of Claim 2 under 35 U.S.C. § 112, first paragraph.

Further, the Examiner asserted that Claim 2 contains subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at 2. Applicants respectfully disagree.

Applicants state in the specification "[t]he polymers of the invention are obtained via methods known to those skilled in the art." Specification at 12. Additionally, the specification teaches how to obtain the polymers of the instant invention. For example, N-carboxyamino acid anhydrides (NCAs) are commonly used in polymer formation or peptide synthesis. Beginning on page 12 of the specification, the Applicants describe the use of N-carboxyamino acid anhydrides (NCAs) to manufacture polyamino acids in a polymerization process. One of skill in the art understands that this process comprises initiating the polymerization with a primary amine compound or ammonia, a propagation step whereby additional amino acids are added to the N-terminal and a termination step. One skilled in the art understands and appreciates that the NCA ring is opened up during the initiation and the propagation steps of the polymerization process whereby residues are linked by peptide bonds. The polymerization process is summarized in the diagram below:



For the initiation step, common compounds that can be used are ammonia (NH_3), linear or branched alkyls, benzyl amine or an amino acid. These compounds, which one of skill in the art would describe as R^2-NH_2, result in R^2 being H, a linear or branched alkyl, a benzyl or a terminal amino acid group in the final polymer. Currently amended Claim 2 recites R^2 represents H, a C2 to C10 linear or C3 to C10 branched alkyl, benzyl or a terminal amino acid unit. The propagation step includes sequential addition of amino acids at the existing N-terminal, therefore, the R^2 group, which is determined by the nature of the compound used in the initiation step, remains intact..

After polymerization is complete, the N-terminal which can be the amino acid unit used to make the polymer will then have the R^1 group as an H. Other termination steps involve quenching. If quenching is required, one of skill in the art would understand that this can be achieved by adding an akyl group (branched or linear) by an acylation reaction to give an amide group. The result of this reaction step is that the R^1 group in the final polymer is an acyl (branched or linear) group. Additionally, one of skill in the art, reading the specification would understand how to obtain pyroglutamate as the R^1 group. For example, when the polymer is constructed of polyglutamate (*See*

e.g., Specification at 12; *see also*, Specification at 19-22), one of skill in the art understands and recognizes the N-terminal glutamic acid residue can spontaneously cyclize to become pyroglutamate. One of skill in the art would understand that the pyroglutamate cannot be obtained at the C-terminal. Therefore, R^2 cannot be a pyroglutamate. Furthermore, R^2 groups cannot be an acyl group as this would require initiating the polymerization with an amide compound (R^2CO-NH_2). One of skill in the art understands that amides are unreactive as nucleophiles and cannot initiate NCA polymerizations. Currently amended Claim 2 recites R^1 represents H, a linear C2 to C10 or branched C3 to C10 acyl group, or a pyroglutamate. Applicants, respectfully submit that in view of the teachings of the specification and the knowledge of one of skill in the art, that Applicants were in possession of the claimed invention. Thus, Applicants respectfully request the Examiner withdraw the rejection of Claim 2 under 35 U.S.C. § 112, first paragraph.

The Examiner rejected Claim 2 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Office Action at 3. Applicants have amended Claim 2 and respectfully request the Examiner withdraw the rejection of Claim 2 under 35 U.S.C. § 112, second paragraph.

The Examiner has objected to Claims 8-14 under 37 CFR 1.75(c) as being in improper multiple dependent form. Office Action at 3. Applicants have amended Claims 8-14 to remove multiple dependencies. Applicants, therefore, respectfully request the Examiner withdraw the objection to Claims 8-14.

The Examiner has rejected Claim 1 under 35 U.S.C. § 102(e) as being allegedly anticipated by Lambert *et al.*, (U.S. Pat. No. 7,030,155) ("Lambert"), stating that Lambert discloses a conjugate comprising alpha-tocopherol bonded to polyglutamate. Office Action at 4. Lambert teaches that a custom surfactant can be "a vitamin E derivative comprising a peptide bonded polyglutamate

attached to the ring hydroxyl and pegylated phytosterol." Lambert at col. 8, ll. 29-31. One of skill in the art would understand that the peptide bonded polyglutamate disclosed by Lambert is a chain-end linking of tocopherol to a polyglutamate. Lambert, therefore, teaches and discloses a surfactant that has a hydrophilic head and a hydrophobic tail. Amended Claim 1 of the instant application requires aspartic acid and/or glutamic acid residues attached to one or more alpha-tocopherol side chains. Lambert, by contrast, teaches the linear pegylation of tocopherol through esterification to create a surfactant, *i.e.*, the composition of Lambert is different than the composition of Claim 1 of the instant application. For example, Lambert teaches that the PEGylated vitamin E is linear, *i.e.*, one vitamin E molecule is attached via a succinic acid diester to a molecule of polyethylene glycol. Lambert at col. 6, ll 61-67 and Scheme II. Amended Claim 1 recites that the polymers have one or more alpha-tocopherol side chains and are not the linear PEGylated vitamin E disclosed in Lambert. Moreover, Lambert does not teach a PEGylated polymer with more than one alpha-tocopherol molecule attached.

Additionally, the Applicants note that the PEGylated vitamin E is available on the market and that the PEGylated forms of vitamin E are not biodegradable *in vivo*. Specification at 4-5. Applicants state that the novel polymers of the instant application have association and/or encapsulation properties that are surprising when compared with similar products and they are easily degraded in the presence of enzymes, *i.e.*, they are biodegradable *in vivo*. Specification at 6. Moreover, the Applicants state that one of the objectives of the present invention is to provide a novel polymer that is biodegradable. Specification at 5. The addition of PEGylated vitamin E, as required by Lambert, would change these properties. Further, the uncertain hydrophobicity of the PEGylated vitamin E could greatly alter the association and/or encapsulation properties if added to the novel polymers of the instant application. Also, one of skill in the art would appreciate that a polyglutamate with multiple side chains of alpha-tocopherol molecules would have different

structure and properties from a polyglutamate with only one alpha-tocopherol molecule attached. Notwithstanding this knowledge, Lambert does not disclose the structure, synthesis, or properties of such a polyglutamate with only one attached alpha-tocopherol molecule. Applicants, therefore, respectfully submit that Lambert does not anticipate amended Claim 1 and respectfully request the Examiner withdraw the rejection of Claim 1 under 35 U.S.C. § 102(e).

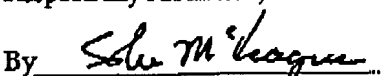
The Examiner has not indicated a reason for objection to Claims 3-7, Applicants, therefore, assume that the basis of the objection is because Claims 3-7 depend from a rejected claim. Applicants assert that both Claims 1 and 2 are now in condition for allowance and thus respectfully request the Examiner withdraw the objection to Claims 3-7.

For the reasons set forth above, Applicants believe this Application is in condition for allowance.

Applicants submit concurrently a request for extension of time under 37 C.F.R. 1.136 and the accompanying fee. In the event that any additional extensions of time are necessary to prevent the abandonment of this patent application, then such extension of time are hereby petitioned. The U.S. Patent and Trademark Office is hereby authorized to charge any fees that may be required in conjunction with this submission to Deposit Account Number 50-2228, referencing matter number 022290.0122PTUS from which the undersigned is authorized to draw.

Dated: July 5, 2007

Respectfully submitted,

By 

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